



BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC-2015-0034; NIOSH 233-A]

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings: Proposed Additions to the NIOSH Hazardous Drug List 2016; Request for Comment

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of draft document available for public comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following draft document for public comment entitled "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings: Proposed Additions to the NIOSH Hazardous Drug List 2016." The document and instructions for submitting comments can be found at www.regulations.gov.

This guidance document does not have the force and effect of law.

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DATES: Electronic or written comments must be received by

[INSERT DATE, 60 DAYS AFTER PUBLICATION DATE].

ADDRESSES: You may submit comments, identified by CDC-2015-0034 and Docket Number NIOSH 233-A, by either of the two following methods:

- *Federal eRulemaking Portal:* www.regulations.gov Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226.

Instructions: All information received in response to this notice must include the agency name and the docket number (CDC-2015-0034; NIOSH 233-A). All relevant comments received will be posted without change to www.regulations.gov, including any personal information provided. All electronic comments should be formatted as Microsoft Word. Please make reference to CDC-2015-0034 and Docket Number NIOSH 233-A. All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226.

FOR FURTHER INFORMATION CONTACT: Barbara MacKenzie, NIOSH, Division of Applied Research and Technology, Robert A. Taft Laboratories, 1090 Tusculum Avenue, MS C-26, Cincinnati, Ohio 45226. (513) 533-8132 (not a toll free number). E-mail: hazardousdrugs@cdc.gov.

SUPPLEMENTARY INFORMATION: The NIOSH Alert: "Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings" was published in September 2004 (<http://www.cdc.gov/niosh/docs/2004-165/>). This Alert contained Appendix A which was a list of drugs that were deemed to be hazardous and may require special handling. This list of

hazardous drugs was updated in 2010, 2012 and 2014 and covered all new approved drugs and drugs with new warnings up to December 2011 (<http://www.cdc.gov/niosh/docs/2014-138>). Between January 2012 and December 2013, 60 new drugs received FDA approval and 270 drugs received new warnings based on reported adverse effects in patients. From this list of 330 drugs, 44 drugs were identified by NIOSH as potential hazardous drugs. In addition to these 44 drugs, the panel members were asked to comment on the addition of one drug requested by several stakeholders. Three additional drugs had safe handling recommendations from the manufacturer and NIOSH is following these recommendations. Therefore, these 3 drugs will be listed as hazardous without requiring further review. A panel consisting of peer reviewers and stakeholders was asked to review and comment on the 45 potentially hazardous drugs. Reviewers were not asked to provide a consensus opinion and NIOSH made the final determination regarding proposed additions to the 2016 hazardous drug list.

NIOSH reviewed the recommendations of the peer reviewers and stakeholders and determined that 33 drugs in addition to the 3 drugs with manufacturer's warnings, were determined to have one or more characteristics of a hazardous drug and this list of 36 drugs is being published for comment in CDC-2015-0034 and NIOSH

Docket Number 233-A. The list of proposed additions can be found at www.regulations.gov.

Dated: May 20, 2015.

John Howard,

Director, National Institute for Occupational Safety and Health,
Centers for Disease Control and Prevention.

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